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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,634	05/01/2001	Ick-Dong Yoo	1728/1F088-US1	5673

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EXAMINER

AFREMOVA, VERA

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 03/21/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/846,634

Applicant(s)

Ick-Dong Yoo et al.

Examiner

Vera Afremova

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 30, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10 and 11 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/221,261.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s)
- 4) ☐ Interview Summary (PTO-413) Paper No(s)
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

The request for a continued prosecution application (CPA) under 37 CFR 1.53(d) filed on 1/30/2003 is acknowledged. 37 CFR 1.53(d)(1) was amended to provide that the prior application of a CPA must be: (1) a utility or plant application that was filed under 35 U.S.C. 111(a) before May 29, 2000, (2) a design application, or (3) the national stage of an international application that was filed under 35 U.S.C. 363 before May 29, 2000. See *Changes to Application Examination and Provisional Application Practice*, interim rule, 65 Fed. Reg. 14865, 14872 (Mar. 20, 2000), 1233 Off. Gaz. Pat. Office 47, 52 (Apr. 11, 2000). Since a CPA of this application is not permitted under 37 CFR 1.53(d)(1), the improper request for a CPA is being treated as a request for continued examination of this application under 37 CFR 1.114. See *id.* at 14866, 1233 Off. Gaz. Pat. Office at 48.

CPA of this application 09/846,634 is not permitted because it does not have an actual filing date before May 29, 2000 for the applicant to be able to file a CPA of the instant application. MPEP 706.07 (h).

Status of claims

New claims 10 and 11 have been filed on 1/30/2003 [Paper No. 11] and are pending in the instant application.

Claims 4, 8 and 9 were canceled in the Paper No. 11 filed 1/30/2003. Claims 1-3 and 5-7 were canceled in the Paper No. 2 filed 5/01/2001.

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Please, note that the general policy of the Office is not to permit the applicant to shift to claiming another invention after an election is once made and action given on the elected subject matter. Note that the applicant cannot, as a matter of right, file a request for continued examination (RCE) to obtain continued examination on the basis of claims that are independent and distinct from the claims previously claimed and examined (i.e., applicant cannot switch inventions by way of an RCE as a matter of right). See MPEP 819. While applicant, as a matter of right, may not shift from claiming one invention to claiming another, the Office is not precluded from permitting a shift. It may do so where the shift results in no additional work or expense, and particularly where the shift reduces work as by simplifying the issues. *Ex parte Heritage*, Pat. No. 2,375,414 decided January 26, 1944. If the examiner has accepted a shift from claiming one invention to claiming another, the case is not abandoned. *Meden v. Curtis*, 1905 C.D.272, 117 O.G. 1795 (Comm'r Pat. 1905). MPEP 819.01.

New claims 10 and 11 are under examination in the instant office action.

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). Please, insert the reference to the parent application 09/221,261 which is now abandoned in the first sentence of the specification.

Specification

The disclosure remains objected to because of the following informalities:

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The address of the Korean Collection for Type Cultures (KCTC) is missing (see page 6, for example). Appropriate correction is required. Please, insert the current KCTC address.

Claim Objections

New claims 10 and 11 are objected to because of the following informalities:

The Latin names of microorganisms should be italicized. Claim 10 contains wrong punctuation such as semi-coma at the end of the claim. Appropriate corrections are required.

Claim Rejections - 35 USC § 112

Deposit

New claims 10 and 11 are rejected under 35 U.S.C. 112, first *paragraph*, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention as explained in the prior office action with respect to the canceled claims, drawn to the use of a particular strain, and for the reasons below as applied to the pending claims.

Claims 10 and 11 require one of ordinary skill in the art to have access to a specific microorganism *Phellinus linteus* Yoo (KCTC 0399 BP). Because the microorganism is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, the requirements of 35 USC 112 may be satisfied by deposit of the microorganism. The specification does not disclose a repeatable process to obtain the

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microorganism and it is not clear from the specification or record that the microorganism is readily available to the public.

The objection and accompanying rejection may be overcome by establishing that each microorganism identified is readily available to the public and will continue to be so for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer, or by an acceptable deposit as set forth herein. See 37 CFR 1.801-1.809.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or a statement by an attorney of record over his/her signature and registration number, stating that the deposit has been made under the Budapest Treaty and that all restrictions imposed by the depositor on availability to the public of the deposited material will be irrevocably removed upon issuance of the patent would satisfy the deposit requirement. See 37 CFR 1.808.

Because Korean Collection for Type Cultures (KCTC) has acquired the status of an International Depository in accordance to the Budapest Treaty, a declaration stating that all restrictions will be irrevocably removed upon issuance of the patent will overcome this rejection.

However, the applicants' statement with regard to the deposit requirement does not clearly identify what fungal material/strain is deposited (see at page 3, last paragraph of the response Paper No 8 filed 8/08/2002). The specification contains disclosure of several microorganisms belonging to *Phellinus linteus*, for example: see Figure 1. Therefore, it is not certain that the applicants' statement relates to the presently claimed strain KCTC 0399BP.

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Indefinite

New claims 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10 and 11 are rendered indefinite by the phrase "Yoo" because it is not particularly clear what is a meaning of this phrase. Is it a part of the Latin name? Is it an original designation number of the strain before deposit in the KCTC under accession number 0399 BP? Further, the use of parentheses encompassing terminology related to the KCTC accession number in the claims is indefinite because it is unclear if what is stated in parentheses is a further limitation or simply alternative meaning. How many "Yoo" strains besides the strain KCTC 0399BP might be encompassed by the claimed invention? Is the "Yoo" strain identical to the strain "KCTC 0399 BP"? Is the phrase "Phillineus linteus Yoo" a larger entity than one particular strain "KCTC 0399 BP". It is suggested to identify the claimed subject matter as "*Phillineus linteus* strain KCTC 0399 BP".

Claim 10 is indefinite and confusing with regard to nature, structure and/or contents of "an immuno-stimulating polysaccharide substance" which is produced by the claimed strain. The claimed "substance" appears to be intended as a "polysaccharide" but it comprises "17.3% proteins" as claimed. Thus, it is uncertain what material is produced by the claimed strain and/or

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what is a claimed subject matter. Is the claimed strain characterized by a production of a "polysaccharide" or a polysaccharide-containing crude extract or a polysaccharide-protein complex? Further, it is uncertain what substance (pure polysaccharide or a polysaccharide-containing crude extract) contains sugar units as claimed. Thus, the "mol %" amounts can not be determined as claimed. Further, the presence and amounts of glucose are uncertain and confusing as claimed. Glucose appears to be a major component is the polysaccharide as claimed, but it constitutes less than 20 mole % of total sugar units as encompassed by the claimed subject matter.

Claim 11 rendered indefinite and confusing by recitation of uncertain characteristics. For example, it is uncertain what is a meaning of "perennial" as related to a fungal strain and what is encompassed by the phrase "woody part" in the presently claimed invention drawn to a fungal strain but not to a plant material. Further, it is unclear how the claimed fungal strain might be both a "germless" (claim 11, line 2) strain and a strain capable to produce "spores" or germs (claim 11, line 7) or at least to have a "hymenial layer" (claim 11, lines 5-6) which is a source of spores or germs in a fungal organism. Although it is reasonably believed that under different culture conditions the strain KCTC 0399 BP might grow on a "woody part" of plants and/or it might not produce spores and, thus, to remain "germless", however, these conditions, if intended, are not identified as claimed and as disclosed. Further, the claimed subject matter is rendered indefinite by the phrases "at the time of being picked" (claim 11, line 3) and "the lapse of time" (claim 11, line 5) since the metes and bounds of the claim can not be determined. Further, the

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claim 11 recites the spore size being "3-4 cm" which does not appear to be a reasonable size for a fungal spore.

The suggested language for the presently claimed subject matter is following, for example: "A biologically pure culture of *Phillineus linteus* having all of the identifying characteristics of *Phillineus linteus* strain KCTC 0399 BP" or "A biologically pure culture of *Phillineus linteus* strain KCTC 0399 BP".

New matter

New claims 10 and 11 are rejected under 35 U.S.C. 112, *first paragraph*, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Insertion in the new claim 10 of the limitation such as "78.6 mole % mannose and 3.4 mole % galactose" for a polysaccharide substance produced by the presently claimed strain has no support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept of the use of a substance of a polysaccharide nature which contains "78.6 mole % mannose and 3.4 mole % galactose". There is only one exemplified disclosure (page 31, table 11) wherein sugar composition and amounts of sugar units are different from that which are claimed. Thus,

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there is no sufficient support for the new genus as presently claimed. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the limitation such as "78.6 mole % mannose and 3.4 mole % galactose" in claim 10 is considered to be the insertion of new matter for the above reasons.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

New claims 10 and 11 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A strain of a microorganism belonging to the species of *Phillineus linteus* is a product of nature. It is suggested that applicants use the language "a biologically pure culture of *Phillineus linteus*" in connection with the strain KCTC 0399 BP to identify a product that is not found in nature. See *In re Bergy*, 201 USPQ 352, 370 (C.C.P.A. 1979).

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Claim Rejections - 35 USC § 102/103

New claims 10 and 11 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lee et al. [U] or KR 97-15743 [N] in the light of evidence by US 4,051,314 [IDS-1] and US 4,877,777 [A].

Claims are directed to a fungal culture belonging to *Phellinus linteus* strain KCTC 0399 BP which is capable to produce an immuno-stimulating polysaccharide substance comprising proteins and carbohydrates including mannose, galactose and glucose, wherein the glucose units are joined by α (1-4) and β (1-6) linkages.

Lee et al. [U] disclose a fungal strain L13202 (obtained from ATCC) belonging to the fungal species of *Phellinus linteus* (abstract or page 326, col.1, last three lines) which is capable to produce a polysaccharide substance comprising mannose, galactose and glucose (abstract or table 4). The cited reference teaches that polysaccharide substances derived from fungal cultures or mushrooms are characterized by immuno-stimulating activity or anti-tumor activity and that the fungal polysaccharides comprise glucose units and the β (1-6) linked branches (page 325, col. 1). The polysaccharide substance in the reference by Lee is extracted from fungal mycelia and, thus, the crude polysaccharide substance preparation is reasonably expected to comprise at least some amounts of proteins. The cited reference by Lee et al. [U] also teaches that particular amounts mannose, galactose and glucose in the fungal polysaccharide substances depend on particular culture conditions and/or culture medium for growing fungal cultures (table 4).

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KR 97-15743 [N] discloses a fungal culture belonging to *Phellinus linteus* strain KCTC 0173 BP (see fig. 1 of KR 97-15743 or abstract of the official translation) which is capable to produce an anticancer immunoactive polysaccharide substance comprising glucose, mannose and galactose (translation page 3). The polysaccharide substance is extracted from the fungal mycelia and, thus, the crude substance preparation is reasonably expected to comprise at least some amounts of proteins derived from fungal culture.

The cited references disclose fungal strain *Phellinus linteus* L13202 {Lee et al. [U]} and fungal strain *Phellinus linteus* KCTC 0173 BP {KR 97-15743 [N]} which are publicly available since they are derived from the IDA culture collections and which appear to be identical to the presently claimed strain *Phellinus linteus* KCTC 0399 BP.

The referenced fungal strains appear to be identical to the presently claimed strain and they are considered to anticipate the claimed strain since they belong to the identical species of *Phellinus linteus* and, thus, they are reasonably expected to have the same taxonomical morphological characteristics including spore formation, color, etc. when cultured at the same conditions as the presently claimed strain belonging to *Phellinus linteus*. Moreover, the claimed taxonomical morphological characteristics are disclosed/admitted by applicants as identical to the characteristics of all representatives of the species of *Phellinus linteus* (see specification page 25, lines 17-18).

The referenced fungal strains appear to be identical to the presently claimed strain and they are considered to anticipate the claimed strain since they are capable to produce immuno-

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stimulating polysaccharide substances comprising glucose, mannose and galactose as the presently claimed strain. Although the particular amounts of glucose, mannose and galactose in the polysaccharides of the cited references are not the same as claimed for the applicants' strain, the amounts of monosaccharides in the polysaccharides depend on particular culture conditions as taught by Lee et al.[U]. Thus, the polysaccharide substance compositions produced by the same fungal species are reasonably expected to be substantially the same, if not identical, when the same fungal species are cultured at identical culture conditions.

Consequently, the presently claimed fungal strain appears to be anticipated by the cited references Lee et al. [U] or KR 97-15743 [N].

In the alternative, even if the claimed fungal strain is not identical to the referenced fungal strains with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced fungal strains are likely to inherently possess the same characteristics of the claimed fungal strain particularly in view of the similar characteristics which they have been shown to share.

Moreover, the cited patent US 4,051,314 [IDS-1] teaches that the fungal polysaccharide substances with immuno-stimulating activity or anticarcinogenic activity (abstract) are produced by representatives of a large fungal group of Basidiomycetes (abstract) including various representatives of *Phellinus* sp. (Table 1 or examples 1 and 18). In addition, the cited patent US 4,877,777 [A] is relied upon for the teaching that the fungal polysaccharide substances which are characterized by immunobiological responses (col. 2, line 59) comprise glucose units joined by α

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(1-4) and β (1-6) linkages (col. 2, lines 33-35 and col. 28, example 8) and that the protein content in the fungal polysaccharide-containing substances is between about 15-38% (col. 28, line 45) as required for the polysaccharide substance of the presently claimed fungal culture.

Thus, the claimed fungal strain KCTC 0399 BP would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the cited references, especially in the absence of evidence to the contrary.

It has been is noted in the prior office actions that applicants conducted an extensive research for taxomonical identification and/or classification of the fungal strains belonging to *Phellinus linteus* including several ATCC strains and that they disclose the strain KCTC 0399BP as being a "novel" strain. However, it is uncertain what characteristics of the claimed strain KCTC 0399BP are "novel" or different features (page 6, last line) as related to the cited prior art strains. It is also uncertain what are the differences between the presently claimed strain KCTC 0399BP and the other applicants' fungal strains including PL5, for example, which appears to be identical to KCTC 0399BP as disclosed by applicants (FIG. 1). It is uncertain what are the differences between the prior art fungal strains/polysaccharides and the applicants' fungal strains capable to produce polysaccharide substances of interest.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

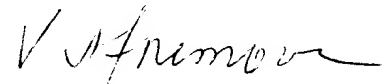
Vera Afremova

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March 20, 2003.

VERA AFREMOVA

PATENT EXAMINER

A handwritten signature in cursive script, appearing to read 'V Afremova', written in dark ink.